NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

LELA KING, Plaintiff, v. ETHICON, INC., and JOHNSON & JOHNSON, Defendants.	Civ. Action No. 21-17983 (FLW) **OPINION**

WOLFSON, Chief Judge:

Plaintiff Lela King ("Plaintiff") brought this action against defendants Ethicon, Inc., and Johnson & Johnson ("Defendants") in connection with injuries Plaintiff allegedly sustained from a pelvic mesh surgical product that Defendants manufacture. The Complaint asserts the following causes of action: strict liability for failure to warn (Count I); strict liability for defective manufacture and design (Count II); negligence (Count III); negligent misrepresentation (Count IV); fraud (Count V); fraudulent concealment (Count VI); constructive fraud (Count VII); violation of the New Jersey Consumer Protection Act ("NJCPA") (Count VIII); and gross negligence (Count IX). Defendants move to dismiss Counts I–II and IV–IX for failure to state a claim, pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. In addition, Defendants move to dismiss Count III with respect to all theories of negligence asserted therein except for design defect and failure to warn, for which Defendants concede that the Complaint states a claim.

For the reasons set forth herein, Defendants' Motion to Dismiss is **GRANTED**. Counts I and II are dismissed with prejudice, as the governing state law does not recognize claims for strict

liability. Count III is dismissed with respect to all negligence claims except design defect and failure to warn, which proceed. Count IV is dismissed with prejudice, as the controlling law does not recognize claims for negligent misrepresentation in a personal injury action. Finally, Counts V–IX are dismissed without prejudice, and Plaintiff is given leave to amend those counts, consistent with this Opinion, within thirty (30) days of the date of the accompanying Order.

I. BACKGROUND AND PROCEDURAL HISTORY

The Court draws the facts recited below from Plaintiffs' Complaint and assumes the facts therein are true for purposes of this motion.

Plaintiff is, and was at all relevant times, a resident of North Carolina. Compl. ¶ 3. Ethicon is a wholly owned subsidiary of Johnson & Johnson ("J&J"), both of which are headquartered in New Jersey. *Id.* ¶¶ 4–5.

Defendants designed and manufacture the Gynecare trans-vaginal tape ("TVT"), a polypropylene mesh product used to treat stress urinary incontinence ("SUI"). *Id.* ¶¶ 21–22. A surgeon implants the TVT "in the vaginal wall," placing "a strip of mesh under the urethra for support," and then "tether[s] [the device] in place [using] two arms that extend up through the buttocks." *Id.* ¶ 22. Defendants obtained approval from the Food & Drug Administration ("FDA") to market the TVT pursuant to Section 510(k) of the Federal Food, Drug and Cosmetic Act (FDCA) as a device that is "substantially equivalent" to a device that the FDA had already approved. *Id.* ¶ 23.

Plaintiff alleges that the design of the TVT is defective and unsafe. Based on citations to medical literature, she alleges that the polypropylene mesh used in the TVT "is biologically incompatible with human tissue and promotes an immune response," which causes "degradation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh." *Id.* ¶¶ 24–25. She also alleges that retropubic slings such as the TVT, which "hammock[] the urethra and

exit[] up through the pubic bone, . . . cause nerve injuries, including pudendal neuralgia, ilioinguinal neuralgia, and Complex Regional Pain Syndrome Type 2," leading to "disabling vaginal [and] . . . pelvic pain." *Id.* ¶¶ 29–30.

Plaintiff alleges that Defendants "have consistently underreported and withheld information about the propensity" of the TVT to "cause injury and complications." *Id.* ¶ 31. She further alleges that Defendants "have misrepresented the efficacy and safety of these products, through various means and media, actively and intentionally misleading the public." *Id.*

On June 30, 2003, Plaintiff's surgeon, Dr. Robert J. Evans, M.D., implanted a TVT device in Plaintiff's pelvic region to treat her SUI. *Id.* ¶ 52. The procedure occurred in North Carolina. *Id.* On May 9, 2014, Plaintiff filed a complaint in the pelvic mesh multi-district litigation pending in the United States District Court for the Southern District of West Virginia (the "MDL"). *Id.* ¶ 53. Her claims arose from injuries she allegedly sustained from the TVT. *Id.* On June 4, 2018, Plaintiff voluntarily dismissed her complaint pursuant to MDL Pre-Trial Order ("PTO") 293/298, which permitted her to refile her complaint within five years if she underwent revision surgery or received a recommendation to do so from her physician. *Id.*

On October 21, 2019, Plaintiff visited Dr. Dionysios Veronikis, M.D., at a hospital in Missouri in response to pain she experienced that was allegedly "related to her TVT sling." *Id.* ¶ 54. Her symptoms included "significant vaginal pain, groin pain, pelvic pain and dyspareunia," which is pain during sexual intercourse. *Id.* Dr. Veronikis surgically removed the TVT on October 22, 2019. *Id.* Plaintiff alleges that as a result of the TVT implantation, she has "experienced mental and physical pain and suffering," including "dyspareunia, disabling pelvic pain, vaginal pain, . . . groin pain, neuromuscular pain, dysuria, urinary frequency, urinary urgency, stress incontinence, [and] . . . permanent injury and scarring." *Id.* ¶ 55. She also alleges that she "has undergone medical treatment and will likely undergo further medical treatment and procedures," and that she "has

suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income." *Id.*

Pursuant to MDL PTO 293/298, Plaintiff filed her Complaint in this Court on October 1, 2021. ECF No. 1. On November 8, 2021, Defendants filed a motion to dismiss for failure to state a claim under Rule 12(b)(6). ECF No. 9. The motion contends that Plaintiff fails to state a claim in Counts I–II and IV–IX. It also seeks to limit the negligence claim in Count III to design defect and failure to warn theories, maintaining that Plaintiff fails to state a negligence claim on any other theory. Plaintiff opposes the motion. ECF No. 10.

II. LEGAL STANDARD

On a motion to dismiss for failure to state a claim, "courts accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (quotations and citations omitted). While Rule 8(a) of the Federal Rules of Civil Procedure does not require that a complaint contain detailed factual allegations, "a plaintiff's obligation to provide the 'grounds' of [her] 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citation omitted). To survive a Rule 12(b)(6) motion to dismiss, the complaint must contain sufficient factual allegations to "raise [the plaintiff's] right to relief above the speculative level," such that a claim "is plausible on its face." *Id.* at 570; *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

To determine whether a plaintiff has met the facial plausibility standard under *Twombly* and *Iqbal*, courts within this Circuit apply a three-step test. *Santiago v. Warminster Twp.*, 629 F.3d 121,

130 (3d Cir. 2010). First, the court must "outline the elements a plaintiff must plead to state a claim for relief." *Bistrian v. Levi*, 696 F.3d 352, 365 (3d Cir. 2012). Next, the court "peel[s] away those allegations that are no more than conclusions and thus not entitled to the assumption of truth." *Id*. Finally, where "there are well-pleaded factual allegations, the court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Iqbal*, 556 U.S. at 679.

III. DISCUSSION

A. Counts I and II: Strict Liability

In Counts I and II, Plaintiff asserts strict liability claims for failure to warn, design defect, and manufacturing defect. *See* Compl. ¶¶ 79–108. The parties agree that North Carolina substantive law applies to Plaintiff's claims. *See* ECF No. 9 at 8–10; ECF No. 10 at 8 n.3. Under North Carolina law, there is "no strict liability in tort in product liability actions." N.C. Gen. Stat. § 99B-1.1; *see also Stoddard v. Wyeth, Inc.*, 630 F. Supp. 2d 631, 632 (E.D.N.C. 2009) (granting motion to dismiss strict liability claims because "North Carolina does not recognize strict liability in product liability cases"). Accordingly, Plaintiff's strict liability claims are not viable. Counts I and II are therefore dismissed.

B. Count III: Negligence

In a "products liability action based upon negligence," a plaintiff must plausibly allege "(1) duty, (2) breach, (3) causation, and (4) damages." *Bryant v. Adams*, 448 S.E.2d 832, 841 (N.C. Ct. App. 1994). To satisfy those elements, the plaintiff must plausibly allege that "'(1) the product was defective at the time it left the control of the defendant, (2) the defect was the result of defendant's negligence, and (3) the defect proximately caused . . . damage [to the plaintiff].'" *Sparks v. Oxy-Health, LLC*, 134 F. Supp. 3d 961, 986 (E.D.N.C. 2015) (quoting *Red Hill Hosiery Mill, Inc. v. MagneTek, Inc.*, 530 S.E.2d 321, 326 (N.C. Ct. App. 2000)).

North Carolina imposes certain statutory limitations on products liability actions sounding in negligence. The statute defines a "[p]roducts liability action" as any action for personal injury

"resulting from the manufacture, construction, design, formulation, development of standards, preparation, processing, assembly, testing, listing, certifying, warning, instructing, marketing, selling, advertising, packaging, or labeling of any product." *See* N.C. Gen. Stat. § 99B-1(3). In addition, for design defect and failure to warn claims, the statute "require[s] proof of additional . . . elements." *Sparks*, 134 F. Supp. 3d at 986 (citing N.C. Gen. Stat. §§ 99B-5, 99B-6). These "additional statutory elements" do not apply to "manufacturing defect claims." *See Sparks*, 134 F. Supp. 3d at 986.

In her negligence count, Plaintiff alleges that Defendants "had a duty to exercise reasonable care in the design, research, manufacture, marketing, testing, advertisement, supply, promotion, packaging, sale, and distribution of . . . the TVT Pelvic Mesh Product at issue in this case." Compl. ¶ 110. Plaintiff asserts claims under three recognized theories of negligence in a products liability action: failure to warn, design defect, and manufacturing defect. *See id.* ¶ 111 (alleging that Defendants breached their duty of care for the reasons articulated in the strict liability counts for failure to warn, defective manufacture, and defective design). She also appears to allege that Defendants were negligent based on other theories. For example, she alleges that Defendants "breached their duty of care" by failing to conduct adequate pre-launch "testing" and by failing to conduct post-launch testing in response to alleged adverse events reported by the FDA and in medical literature. *Id.* ¶ 112.

In their motion to dismiss, Defendants do not challenge the sufficiency of Plaintiff's claims for negligent design defect and failure to warn. ECF No. 9 at 11. Rather, they argue that Plaintiff fails to state a claim for manufacturing defect and that the other theories of negligence Plaintiff asserts are either not cognizable under North Carolina law or otherwise are not pled adequately. I agree. Plaintiff's negligence claim therefore survives with respect to her claims for design defect and failure to warn. For the reasons set forth below, Plaintiff's negligence claim is dismissed with respect to

manufacturing defect and the other asserted negligence theories.

1. Manufacturing Defect

A "manufacturing defect" is "caused by a miscarriage in the manufacturing process that produces an unintended result." *Boudreau v. Baughman*, 322 N.C. 331, 346 (1988). A product therefore "contains a manufacturing defect when the product departs from its intended design." Restatement (Third) of Torts, Products Liability § 2; *Koch v. Sports Health Home Care Corp.*, 54 F.3d 773 (Table), at *5 (4th Cir. 1995) (quoting *Singleton v. Int'l Harvester Co.*, 685 F.2d 112, 115 (4th Cir.1981)) ("'[I]n manufacturing defect cases, the plaintiff proves that the product is defective by simply showing that it does not conform to the manufacturer's specifications.'").

Here, Plaintiff fails to state a manufacturing defect claim because she does not plausibly allege that her implanted TVT deviated from Defendants' design specifications. She alleges that Defendants failed to "manufacture the TVT . . . at issue herein so as to avoid an unreasonable risk of harm." Compl. ¶ 113. But that allegation does not claim that the relevant TVT deviated in any manner from the intended design. In fact, Plaintiff's allegations belie her manufacturing defect claim, as she alleges that the TVT implanted in her was "in the condition directed by and expected by . . . Defendants." *Id.* ¶ 42. Nor are there any "allegations concerning the manufacturing process" indicating that the TVT Plaintiff received was manufactured in a defective manner. *See City of High Point v. Suez Treatment Sols. Inc.*, 485 F. Supp. 3d 608, 631 (M.D.N.C. 2020). Accordingly, Plaintiff's manufacturing defect claim is dismissed. *See Resendez v. C.R. Bard, Inc.*, Civ. No. 19-299, 2020 WL 1916690, at *1 (E.D.N.C. Apr. 20, 2020) (dismissing manufacturing defect claim in connection with pelvic mesh product because the complaint "target[ed] the design, the materials, and certain propensities inherent in the [product]," which "support[] a negligent design claim, not a negligent manufacturing claim").

2. Other Negligence Theories

In her Opposition, Plaintiff highlights allegations in the negligence count that purportedly qualify as alternative theories upon which she bases her negligence claim. *See* ECF No. 10 at 10–12. To summarize, Plaintiff alleges that Defendants failed to adequately "test[]," "inspect[]," and "study[]" the TVT, and that they failed to "use reasonable care in the training and instruction to physicians for the safe use of the TVT." *See id.* (citing Compl. ¶¶ 112–13).

At the outset, Plaintiff concedes that "North Carolina law appears to preclude independent causes of action for negligent failure to test and negligent failure to inspect." *See* ECF No. 10 at 10; *see also id.* at 9 (stating "Defendants are correct that negligent failure to inspect or test alone is not a cause of action"). Indeed, a district court in North Carolina concluded that "North Carolina law does not recognize an independent cause of action based on a failure to test or surveil one's product after marketing." *Couick v. Wyeth, Inc.*, Civ. No. 09-210, 2012 WL 79670, at *7 (W.D.N.C. Jan. 11, 2012). As *Couick* reasoned, claims for design defect, manufacturing defect, and failure to warn subsume a claim for failure to test. *Id.* (quoting *Kociemba v. G.D. Searle & Co.*, 707 F. Supp. 1517, 1527 (D. Minn. 1989)) ("'[U]nless the manufacturer's breach of its duty to test leads the manufacturer to produce a product that is defective in design, manufacture, or warning, no injury can result.'"); *see also Rodriguez v. Stryker Corp.*, 680 F.3d 568, 574 (6th Cir. 2012) (explaining that failure to test "collapses into [a] failure-to-warn claim"). Further, although *Couick* does not explicitly mention the failure to "study" a product, its reasoning extends to such a claim, which in these circumstances is indistinguishable from the failure to test. Because Plaintiff appears to abandon her negligence claim based on failure to test or inspect the TVT post-launch, and she does not cite to any contrary authority, her negligence claim based on a failure to test, inspect, and study the TVT is dismissed.[1]

[1] Plaintiff alternatively contends that her claim for failure to test is a "component of [her] manufacturing defect claim." ECF No. 10 at 9. But as explained *supra*, Plaintiff's manufacturing

Nor can Plaintiff state an independent negligence claim based on a failure to provide adequate "training and instruction to physicians." Allegations that Defendants failed to use reasonable care "in the training and instruction" of physicians appear relevant to her failure-to-warn claim, which survives. But Plaintiff does not cite to any authority holding that failure to train and instruct is a cognizable theory of negligence in a products liability action in North Carolina, independent of failure to warn. In any event, Plaintiff's allegations are entirely conclusory and are therefore not sufficient to state a claim. *Bistrian*, 696 F.3d at 365.

C. Count IV: Negligent Misrepresentation

Defendants move to dismiss Plaintiff's negligent misrepresentation claim on two grounds: first, that negligent misrepresentation is not a cognizable cause of action under North Carolina law in personal injury cases; and second, that Plaintiff fails to plead her claim with particularity under Rule 9(b) of the Federal Rules of Civil Procedure. Because I agree with Defendants on the first point, I do not address the second point in the context of Plaintiff's negligent misrepresentation claim.

The Supreme Court of North Carolina has not decided whether "negligent misrepresentation is a viable theory of recovery in products liability cases causing personal injury rather than pecuniary loss." *See McBrayer v. Ethicon, Inc.*, Civ. No. 12-00779, 2017 WL 73934, at *4 (S.D. W. Va. Jan. 6, 2017). Absent precedent from the state's highest court, "the state's intermediate appellate court decisions constitute the next best indicia of what state law is . . . ." *Liberty Mut. Ins. Co. v. Triangle Indus., Inc.*, 957 F.2d 1153, 1156 (4th Cir. 1992) (quotations and citations omitted). Based on decisions from its court of appeals, in products liability cases asserting claims for personal injury, North Carolina does not recognize negligence misrepresentation as a cause of action independent of

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defect claim fails because she does not plausibly allege that the TVT implanted in her deviated from its intended design.

a traditional negligence claim. *See McBrayer*, 2017 WL 73934, at *4. "North Carolina has 'adopted the Restatement 2d definition of negligent misrepresentation and [its courts have] held that the action lies where *pecuniary* loss results from the supplying of false information to others for the purpose of guiding them in their business transactions.'" *Michael v. Huffman Oil Co.*, 661 S.E.2d 1, 11 (N.C. Ct. App. 2008) (quoting *Driver v. Burlington Aviation, Inc.*, 430 S.E.2d 476, 480 (N.C. Ct. App. 1993) (collecting cases) (emphasis in original)); *Gaston v. PBI Gordon Corp.*, Civ. No. 13-891, 2014 WL 4114324, at *4 (M.D.N.C. Aug. 20, 2014). However, *Driver* did not find "'any case in which the theory of negligent misrepresentation was approved as a basis for recovery for personal injury.'" *Huffman Oil Co.*, 661 S.E.2d at 11 (quoting *Driver*, 430 S.E.2d at 481). Neither did *Huffman Oil Co.* in 2008, *see* 430 S.E.2d at 11, and nor did *McBrayer* in 2017, *see* 2017 WL 73934, at *4.

Here, Plaintiff offers no response to Defendant's position that North Carolina does not recognize negligent misrepresentation claims in personal injury cases, and she therefore waives the claim. *See Jimenez v. T.D. Bank, N.A.*, Civ. No. 20-07699, 2021 WL 4398754, at *14 (D.N.J. Sept. 27, 2021) ("The failure to respond to a substantive argument to dismiss a count, when a party otherwise files opposition, results in a waiver of that count."); *Ferrante v. Amgen, Inc.*, Civ. No. 13-07344, 2014 WL 1092555, at *7 (D.N.J. Mar. 18, 2014) ("Courts in this District have held that the failure to respond to an argument advanced in support of a motion to dismiss results in a waiver of the claim sought to be dismissed."); *Leisure Pass N. Am., LLC v. Leisure Pass Group, Ltd.*, Civ. No. 12-3375, 2013 WL 4517841, at *4 (D.N.J. Aug. 26, 2013) ("Plaintiff has waived its opposition to this argument by failing to respond to it."). In any event, the law in North Carolina remains unchanged since *Huffman Oil Co.*, such that Plaintiff's negligent misrepresentation claim in this personal injury action is not viable independent of her claim for negligence. Accordingly, Plaintiff's negligent misrepresentation claim is dismissed.

D. Counts V and VI: Fraud and Fraudulent Concealment

To state a claim for fraud or fraudulent concealment in North Carolina, a plaintiff must plausibly allege "a '(1) [f]alse representation or concealment of a material fact, (2) reasonably calculated to deceive, (3) made with intent to deceive, (4) which does in fact deceive, (5) resulting in damage to the injured party.'" *Topshelf Mgmt., Inc. v. Campbell-Ewald Co.*, 117 F. Supp. 3d 722, 726 (M.D.N.C. 2015) (quoting *Forbis v. Neal*, 361 N.C. 519, 526–27 (2007)); *see also Hunter v. Guardian Life Ins. Co. of America*, 593 S.E.2d 595, 599 (N.C. Ct. App. 2004) (applying as elements of a fraudulent concealment claim (1) concealment of a material fact, (2) reasonably calculated to deceive, (3) made with intent to deceive, (4) which does in fact deceive, (5) resulting in damage to the injured party). The heightened pleading standard under Rule 9(b) applies to Plaintiff's fraud claims. *See Topshelf Mgmt.*, 117 F. Supp. 3d at 726; *Gaston*, 2014 WL 4114324, at *4. Under that standard, a plaintiff must plead "with particularity . . . [the] time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby." *McCauley v. Home Loan Inv. Bank, F.S.B.*, 710 F.3d 551, 559 (4th Cir.2013) (quotations and citations omitted).

Here, Plaintiff fails to adequately plead her fraud and fraudulent concealment claims with particularity. First, Plaintiff does not adequately plead the "contents" of the misrepresentations. She alleges that Defendants "falsely and fraudulently represented to Plaintiff, her physicians, and to members of the general public that the TVT . . . was safe, effective, reliable, consistent, and better than other similar pelvic repair products." Compl. ¶ 127. But courts routinely find that similar "vague representations" are "not enough under Rule 9(b)" without further specifying "which specific statements are allegedly fraudulent." *See Blair v. Johnson & Johnson*, Civ. No. 19-333, 2020 WL 1172715, at *6 (W.D. Ky. Mar. 11, 2020) (finding insufficient general allegations concerning representations that the product was safer and more effective than other products and procedures);

Hernandez v. Johnson & Johnson, 2021 WL 320612, at *5 (E.D. Wash. Jan. 8, 2021) (finding insufficient general allegations concerning representations that certain mesh products were "safe, effective, [and] reliable"); *Baca v. Johnson & Johnson*, Civ. No. 20-01036, 2020 WL 6450294, at *5 (D. Ariz. Nov. 2, 2020) (finding insufficient allegations that fail to specify "the specific content" of the allegedly misleading statements).

Second, although Plaintiff generally alleges that Defendants made misrepresentations regarding "the safety and utility of the products" in "marketing" and "promotional materials," including "documents, brochures, websites, and/or telephone information lines," Compl. ¶¶ 59, 166, she fails to adequately plead the place or manner of the misrepresentations because she does not "identify or cite any particular document or statement." *Blair*, 2020 WL 1172715, at *7; *Dupere v. Ethicon, Inc.*, Civ. No. 21-2605, 2022 WL 523604, at *6–7 (S.D.N.Y. Feb. 22, 2022) (finding allegations that plaintiff and her physician "relied on the Defendants' statements about the safety and effectiveness of TVT" that were made in "various marketing materials and by sales representatives" failed to state a fraud claim because they did not "identify with particularity any misrepresentations about TVT" and did not "not specify which statements [the plaintiff] or her physician viewed or heard"); *Hernandez*, 2021 WL 320612, at *5 (finding allegations concerning representations in unspecified "advertising" and "marketing" materials failed to adequately allege "the who, what, when, where, and how of the misconduct charged").

Third, Plaintiff fails to plead with any particularity the time when Defendants allegedly made misleading statements. *See Dupere*, 2022 WL 523604, at *7 (dismissing fraud claims in part because the plaintiff failed to plead with particularity "when" she or her physician "were exposed" to Ethicon's allegedly misleading statements pertaining to the TVT); *Baca*, 2020 WL 6450294, at *5 (dismissing fraud claims in part because the plaintiff failed to allege "when" Ethicon allegedly made misleading statements concerning the TVT); *Blair*; 2020 WL 1172715, at *6 (same).

Accordingly, Counts V and VI asserting claims for fraud and fraudulent concealment are dismissed for failure to satisfy Rule 9(b).[2]

E. Count VII: Constructive Fraud

"'A claim of constructive fraud does not require the same rigorous adherence to elements as actual fraud.'" *Hunter v. Guardian Life Ins. Co. of America*, 593 S.E.2d 595, 599 (N.C. Ct. App. 2004) (quoting *Terry v. Terry*, 302 N.C. 77, 83 (1981)). "'Constructive fraud differs from actual fraud in that it is based on a confidential relationship rather than a specific misrepresentation.'" *Hunter*, 593 S.E.2d at 599 (quoting *Barger v. McCoy Hillard & Parks*, 346 N.C. 650, 666 (1997)). "[A]lthough constructive fraud claims must comply with Rule 9(b), the pleading standard is less exacting than with actual fraud claims since there is no misrepresentation requirement." *Lawley v. Liberty Mut. Grp., Inc.*, Civ. No. 11-00106, 2012 WL 4513622, at *5 (W.D.N.C. Sept. 28, 2012) (citing *Watts v. Cumberland County Hosp. Sys.*, 317 N.C. 110, 115–16 (1986)). To state a claim for constructive fraud under North Carolina law, the plaintiff must plausible "allege '(1) a relationship of trust and confidence; (2) that the defendant took advantage of that position of trust and confidence in order to benefit himself; and (3) that the plaintiff was, as a result, injured.'" *Lawley*, 2012 WL 4513622, at *5 (quoting *White v. Consol. Planning, Inc.*, 603 S.E.2d 147, 156 (N.C. Ct. App. 2004));

[2] Defendants alternatively move to dismiss the fraudulent concealment claim on grounds that Defendants did not owe Plaintiff a duty to disclose. ECF No. 9 at 16–17. In particular, Defendants argue that under the learned intermediary doctrine, any duty to disclose ran only to Plaintiff's physician, not to Plaintiff. *Id.* Defendants are correct that North Carolina courts follow the learned intermediary doctrine. *See Carlson v. Bos. Sci. Corp.*, Civ. Nos. 15-57 and 15-211, 2015 WL 5732107, at *2 (W.D.N.C. Sept. 30, 2015), *aff'd*, 856 F.3d 320 (4th Cir. 2017). "'According to [that] doctrine, where a defendant manufactures a product which is dispensed to patients by doctors, rather than directly, the defendant has a duty to warn only the doctor, rather than the patients[,] of any risks associated with the product's use.'" *Id.* (quoting *Baraukas v. Danek Medical, Inc.*, Civ. No. 97-00613, 2000 WL 223508, at * 4 (M.D.N.C. Jan. 13, 2000)). However, Defendants do not cite to any authority holding that a patient may not bring a claim for fraudulent concealment on grounds that the duty to disclose runs only to her physician. I therefore do not find that the learned intermediary doctrine forecloses Plaintiff's claim for fraudulent concealment.

Hunter, 593 S.E.2d at 599 (quoting *Keener Lumber Co. v. Perry*, 149 N.C. App. 19, 28, 560 S.E.2d 817, 823, *disc. review denied*, 356 N.C. 164 (2002)) ("'[A] plaintiff must show (1) the existence of a fiduciary duty, and (2) a breach of that duty.'"). Defendants move to dismiss the constructive fraud claim for failure to plead fraud with particularity and because Plaintiff fails to plausibly allege a fiduciary duty.

Even assuming the Rule 9(b) pleading deficiencies identified *supra* do not apply with equal force to Plaintiff's constructive fraud claim, Plaintiff fails to state a claim because she fails to plausibly allege a "relationship of trust and confidence" with Defendants. *Lawley*, 2012 WL 4513622, at *5 (quotations and citations omitted). Neither the parties nor the Court have identified any precedent from North Carolina addressing whether a patient may form "a relationship of trust and confidence" with a medical device manufacturer for purposes of stating a constructive fraud claim. However, a district court in the Southern District of New York recently dismissed a constructive fraud claim based on alleged omissions concerning the TVT in part because the plaintiff failed to adequately plead a "special relationship" with Ethicon or J&J that could have created a duty to disclose. *See Dupere*, 2022 WL 523604, at *7. In *Dupere*, the plaintiff "allege[d] in conclusory fashion that the Defendants were in a superior position to know that [the] TVT presented complications." *Id.* But these allegations were insufficient because they "failed to identify any details of when or how Ethicon and J&J knew about complications associated with TVT that were otherwise unknown to the public." *Id. Dupere* distinguished another case, which "found such a duty to speak where the plaintiffs alleged that they spoke with representatives of the manufacturers and that at least one of them had 'established a relationship of trust' with the manufacturer prior to deciding whether to undergo surgery." *Id.* (citing *Williamson v. Stryker Corp.*, Civ. No. 12-7083, 2013 WL 3833081, at *11–12 (S.D.N.Y. July 23, 2013)). By contrast, the plaintiff in *Dupere* pleaded "[n]o such facts." 2022 WL 523604, at *7.

For reasons similar to those at issue in *Dupere*, Plaintiff fails to adequately allege a "relationship of trust and confidence" with Defendants, here. Like in *Dupere*, Plaintiff alleges that "Defendants were in a unique position of knowledge concerning the quality, safety, and efficacy" of the TVT. Compl. ¶ 146. However, there are no allegations demonstrating that a special relationship developed between Plaintiff or her physician and Defendants. This case is unlike *Williamson* because, like in *Dupere*, Plaintiff does not plausibly allege that she or her physician "spoke with representatives" of Defendants and "established a relationship of trust" with them. *See Dupere*, 2022 WL 523604, at *7 (citing *Williamson*, 2013 WL 3833081, at *11–12). Further, also similar to *Dupere*, Plaintiff has failed to allege any details concerning Defendants' knowledge of, and failure to disclose, "complications associated with TVT that were otherwise unknown to the public." 2022 WL 523604, at *7; *see also* Compl. ¶¶ 33–34 (discussing 2008 and 2011 public FDA notifications concerning potential risks associated with pelvic mesh products).

This analysis is consistent with decisions in North Carolina addressing constructive fraud claims in analogous contexts. In *Lawley*, a district court held that no "confidential or fiduciary relationship" arose between the plaintiff and her insurance provider based on the plaintiff's bare allegations that, "[p]ursuant to the terms of the Policy," the provider was "placed in a position of special faith, confidence, and trust with [the plaintiff] to honestly and properly administer the [p]olicy and to act in good faith and in [the plaintiff's best interests]." 2012 WL 4513622, at *6. Likewise, *Hunter* held that a plaintiff failed to plausibly allege a confidential relationship with its insurance provider based on allegations that the provider sold a policy premised on misleading premium projections because the plaintiff "fail[ed] to allege the requisite 'facts and circumstances' which created this relationship." *See* 593 S.E.2d at 599. *Hunter* distinguished precedent holding that a plaintiff adequately pled a constructive fraud claim based on allegations that the defendant "took advantage of his dying brother by inducing him to sell his portion of a business at an inadequate

price," because the complaint specified "the family relationship, the business dealings between the two and the increased role the defendant had near his brother's death." *Id.* (citing *Terry*, 302 N.C. at 86). Similar to *Lawley* and *Hunter*, and unlike in *Terry*, Plaintiff has failed to plead "the requisite 'facts and circumstances,'" 593 S.E.2d at 599, necessary to demonstrate a confidential relationship with Defendants.

Accordingly, Plaintiff's constructive fraud claim in Count VII is dismissed.

F. Count VIII: NJCPA

Defendants move to dismiss Count VIII on grounds that North Carolina law applies, rendering an NJCPA claim unviable, and that Plaintiff fails to plead the claim with particularity. ECF No. 9 at 17. Plaintiff concedes that its NJCPA claim is not viable and seeks leave to replead the claim under the North Carolina Unfair and Deceptive Trade Practices Act ("NCUDTPA").

Even construing Count VIII as a claim under the NCUDTPA, Plaintiff fails to state a claim. "Where . . . a party raises a [NC]UDTPA claim 'alleging detrimental reliance on false or deceptive representations,' Rule 9(b) applies." *Packrite, LLC v. Graphic Packaging Int'l, Inc.*, Civ. No. 17-1019, 2018 WL 4112827, at *7 (M.D.N.C. Aug. 29, 2018) (quoting *Topshelf Mgmt.*, 117 F. Supp. 3d at 731). As pled, Rule 9(b) applies to Plaintiff's claim because it turns on allegations that Plaintiff and her physician relied on Defendants' alleged misrepresentations. *See* Compl. ¶ 158 (alleging that Defendants "represented to physicians . . . that . . . the TVT [was] . . . safe and effective," "provided information to physicians . . . that was incomplete, misleading, and insufficient," "represented that the risks" of the TVT "were minimal and transient," and "represented and marketed to physicians . . . [that the TVT] is safe, biologically compatible, and inert"); *id.* ¶ 161 (alleging that "[h]ad Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the [TVT]"). For the same reasons that apply to her fraud claims in Counts V and VI, Plaintiff fails to plead an NCUDTPA claim with particularity under Rule 9(b). *See*

Packrite, 2018 WL 4112827, at *7 (dismissing NCUDTPA claim where the plaintiff's claim was based on alleged misrepresentations, and it failed to plead the claim with particularity).

Plaintiff is given leave to amend Count VII in order to assert a claim under the NCUDTPA, but to survive a subsequent motion to dismiss, she must cure the same deficiencies this Court has identified with respect to Counts V and VI.

G. Count IX: Gross Negligence

To state a claim for gross negligence, a plaintiff must plausibly allege "wanton conduct, [plus] 'each of the elements of negligence . . . .'" *Vanhoy v. Am. Int'l Indus.*, Civ. No. 18-90, 2018 WL 5085712, at *3 (M.D.N.C. Oct. 18, 2018), *report & recommendation adopted*, 2018 WL 6731672 (M.D.N.C. Nov. 5, 2018). "Willful and wanton conduct is defined as 'the conscious and intentional disregard of and indifference to the rights and safety of others, which the defendant knows or should know is reasonably likely to result in injury, damage, or other harm.'" *Id.* (quoting N.C. Gen. Stat. § lD-5(7)). Thus, the difference between negligence and gross negligence "is not in degree or magnitude of inadvertence or carelessness, but rather is intentional wrongdoing or deliberate misconduct affecting the safety of others." *Yancey v. Lea*, 354 N.C. 48, 53 (2001). "An act or conduct rises to the level of gross negligence when the *act* is done purposely and with knowledge that such act is a breach of duty to others, *i.e.*, a conscious disregard of the safety of others." *Id.* (emphasis in original).

Here, Plaintiff fails to plausibly allege wanton conduct. The closest she comes to concrete allegations of "intentional wrongdoing or deliberate misconduct," *Yancey*, 354 N.C. at 53, is an allegation concerning an FDA Safety Communication issued on July 13, 2011, reporting serious complications associated with transvaginal placement of surgical mesh to treat pelvic organ prolapse (POP). Compl. ¶ 34 (citing *FDA Safety Communication: UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse* ["2011 FDA

Communication"], Food and Drug Admin. (July 13, 2011)).[3] As reported in the Communication, "[b]ased on an updated analysis of adverse events reported to the FDA and complications described in the scientific literature, the FDA identified surgical mesh for transvaginal repair of POP as an area of continuing serious concern." 2011 FDA Communication. The FDA issued the update to provide notification that "serious complications associated with surgical mesh for transvaginal repair of POP are **not rare**." *Id.* (emphasis in original). According to Plaintiff, this information put Defendants on notice of complications associated with surgical mesh products, but Defendants failed to disclose or disseminate the information to physicians and patients. *See* Compl. ¶¶ 34, 36. But even assuming, without deciding, that the 2011 FDA Communication demonstrates purposeful or knowing conduct, it concerns the use of surgical mesh to treat POP, not SUI, which is the application in Plaintiff's case. *See* 2011 FDA Communication (noting that "[t]he FDA continues to evaluate the effects of using surgical mesh to repair SUI and will communicate these findings at a later date"); Compl. ¶ 51 (alleging that the TVT was implanted to treat Plaintiff's SUI). Accordingly, the 2011 FDA Communication does not support a claim that Defendants knowingly misled Plaintiff or her physician as to risks associated with the TVT.

Plaintiff's remaining allegations are conclusory and fail to state a claim. She asserts that the following allegations establish wanton conduct: Defendants knew, or should have known, of the "risk of serious injuries" allegedly associated with the TVT but "continued to market" the TVT "for transvaginal use to physicians and patients . . . without adequate warnings"; Defendants "made false claims about the safety and quality of the [TVT]" to the FDA; Defendants "were in possession of evidence demonstrating that the [TVT] was defective and unreasonably dangerous" but failed

[3] Plaintiff relies on the 2011 Safety Communication in her Complaint, and the Court will therefore take judicial notice of this document. *See Pension Ben. Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir 1993).

"inform or warn of the dangers"; Defendants "intentionally and recklessly designed, marketed, [and] sold . . . [the TVT] with wanton and willful disregard for the rights and health of Plaintiff"; Defendants "consistently underreported and withheld information about the propensity of" the TVT "to fail and cause injury. Compl. ¶¶ 31, 75, 103, 139, 181. These allegations "are no more than conclusions." *Bistrian*, 696 F.3d at 365. They state that Defendants knowingly failed to disclose risks associated with the TVT, but they fail to allege "factual content" sufficient "to raise [Plaintiff's] right to relief above the speculative level." *Twombly*, 550 U.S. at 570; *see also Dupere*, 2022 WL 523604, at *5 (dismissing gross negligence claim based on Ethicon's alleged omissions in connection with the TVT because the plaintiff failed "to plead facts that reflect [] an extreme departure from the standards of ordinary care" such that "the danger was either known to the defendant or so obvious that the defendant must have been aware of it") (quotations and citations omitted). Accordingly, Plaintiff's gross negligence claim is dismissed.

IV. CONCLUSION

For the reasons set forth herein, Defendants' Motion to Dismiss is **GRANTED**. Counts I, II, and IV are dismissed with prejudice. Count III is dismissed with respect to all negligence claims except design defect and failure to warn, which proceed. Finally, Counts V–IX are dismissed without prejudice. Plaintiff is given leave to amend her complaint in order to re-plead Counts V–IX, consistent with this Opinion, within thirty (30) days of the date of the accompanying Order. An appropriate form of Order is filed herewith.

Date: June 29, 2022

/s/ Freda L. Wolfson
Hon. Freda L. Wolfson
U.S. Chief District Judge